DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

August 27, 2014

MEDIVATORS, INC.
Mrs. Kinnari Shah
Senior Regulatory Affairs Specialist
14605 28th Ave. North
Minneapolis, MN 55447

Re: K133724
Trade/Device Name: Minncare HD® Disinfectant
Regulation Number: 21 CFR 876.5665
Regulation Name: Disinfectant, subsystem, water purification
Regulatory Class: II
Product Code: NIH
Dated: July 30, 2014
Received: July 31, 2014

Dear Mrs. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known):__K133724_____

Device Name: **Minncare® HD Disinfectant**

Indications for Use:

Minncare HD is intended for the disinfection of water purification systems for hemodialysis. It should be diluted to a 1% concentration (1 part Minncare HD to 99 parts water) and used for a minimum contact time of 36 minutes at 20°C.

Prescription Use __X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-the-Counter Use_____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Minncare® HD Disinfectant

510(k) Summary

Manufacturer:	Medivators Inc., a Cantel Medical Company
Address:	14605 28th Avenue North Minneapolis, MN 55447 USA (800) 328-3345
Official Contact:	Kinnari Shah Senior Regulatory Affairs Specialist
Date Prepared:	13th August 2014
Trade Name:	Minncare® HD Disinfectant
Common Name:	Water Purification System Disinfectant
Classification Name:	Disinfectant, subsystem, water purification
Product Code:	NIH
Device Class:	II
Classification Reg:	876.5665
510k:	K133724

Medivators Inc. has supplied the following information to the US Food and Drug Administration to support substantial equivalence of the Minncare HD Disinfectants to other disinfectants currently cleared for sale in the U.S.

1. Intended Use

Minncare HD is intended for the disinfection of water purification systems for hemodialysis. It should be diluted to a 1% concentration (1 part Minncare HD to 99 parts water) and used for a minimum contact time of 36 minutes at 20°C.

2. Device Description

Minncare HD is a clear liquid disinfectant solution that consists of a stabilized mixture of hydrogen peroxide, peracetic acid and acetic acid. Minncare HD is intended to be used for hemodialysis water purification system disinfection when diluted to a 1% concentration (1 part Minncare HD to 99 parts water) and applied for a minimum contact time of 36 minutes at 20°C. The active microbicidal ingredient is peracetic acid (PAA), and the recommended use concentration of 1%. The concentration of the use solution should be confirmed with 1% Minncare HD indicator test strips to have reached the furthest point of the distribution loop during the system disinfection contact time. Upon completion of disinfection the system must be rinsed to remove residual levels of the disinfectant. Residual levels should be

checked using Minncare HD residual test strips to ensure residual levels of 1 ppm PAA or less. Minncare HD is supplied in cases containing high density polyethylene plastic bottles. Individual bottles are labeled with all information necessary to use the device safely.

3. Comparison to Other Device in Commercial Distribution Within the United States

MEDIVATORS Inc. believes Minncare HD is substantially equivalent in formulation, performance and indications to its predicate device - Hemoclean Disinfectant which is cleared under 510k - K023064. Hemoclean is a peracetic acid based liquid chemical germicide disinfectant solutions with similar chemistry, intended use and disinfectant performance to Minncare HD. Below is the comparison between the subject and the predicate device –

Item	Minncare HD MEDIVATORS Inc.	Hemoclean Disinfectant KRD CO., LTD (K023064)
Active Ingredient	Peracetic Acid/ Hydrogen Peroxide	Peracetic Acid/ Hydrogen Peroxide
Device Use Indication	Water Purification Systems for Hemodialysis	Hemodialysis machines, Water Purification Systems and Dialyzers
Form	Liquid solution	Liquid solution
Dilution Required	Yes	Yes
Minimum Contact Time	36 minutes	10 minutes
Use Temperature	20°C	20°C
Minimum Use Concentration	1%	3%
Active Ingredient Nominal Concentration	5% / 22%	1.7%/ 5.3%
Single Use	Yes	Yes
Sterilization Claim	No	No
Use and Compatibility with Water Purification System	Yes	Yes
Shelf-Life	12 months	12 months
Test Strip Used to Monitor MRC	Yes	Yes

4. Summary of Non-Clinical Performance Data

FDA Guidance for content of premarket notification submissions for water purification system disinfectants (product code NIH) has not been established, and thus performance testing requirements were based on related FDA Guidance for Content and Format of Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/High Level Disinfectants (Jan 2000). However, it is important to note that Minncare HD is not intended to be used on critical or semi-critical devices and high-level disinfection is not claimed.

Performance testing has been conducted to show that Minncare HD is safe and effective for its intended use. The following types of data/information are provided in this submission in support of substantial equivalence to predicate device and to demonstrate that Minncare HD performs safely as intended.

- Detailed description of physical and chemical properties
- Proposed labeling
- Sporicidal, tuberculocidal, fungicidal, virucidal and bactericidal efficacy
- Simulated-use disinfection efficacy
- Material compatibility
- Test strip performance
- Stability
- Risk Analysis

5. Conclusion

The performance testing data indicates that the subject device, Minncare HD, is substantially equivalent to the predicate device Hemoclean Disinfectant (K023064).